



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

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MAR 29 1991

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TO: Rodger [redacted] and Jan Carlson

FROM: [redacted] Siegel

RE: Implications of a lead research project by ATSDR in
Granite City, Illinois

REPLY TO ATTENTION OF:

On March 28, 1991, a meeting between ATSDR and Region V was held with Dave Ullrich. The purpose of the meeting was for ATSDR to present to the Region its intended plan to conduct a tri-city lead study which will include Granite City, Illinois. ATSDR is hoping to get some funding for aspects of the study from Region V, but has made it clear that it will do the study with or without the Region's assistance. I was asked at this meeting what the possible implications of the study are for the pending NL litigation and whether I supported the study.

Background

On March 30, 1990, a ROD was signed for the NL Site. The ROD requested ATSDR to perform a simple blood screening survey for the people of Granite City during the summer of 1990. ATSDR refused to fund the study, offended that it was not consulted by EPA before this aspect of the ROD was formalized. It is now insisting on conducting a major research study on the health effects of lead in three cities, including Granite City. The study will take at least a year to conduct and most likely longer. Although it was not mentioned in the meeting on March 28, it is worth noting that Louise Fabinski of ATSDR tells me that her Agency is also considering a second study of lead in Granite City which would follow the study at issue at our March 28 meeting. The second study would focus on the amount of lead in bone and teeth. I suspect that at this time plans for a second study are very speculative.

Critical analysis of EPA's remedy selection in NL ROD

In selecting a cleanup level in Granite City of 500 ppm for lead in residential soil, EPA relied on three primary factors:

1. EPA guidance of 500-1000 as an acceptable range, based on site specific factors;
2. literature review; and
3. State of Illinois recommendation of 500 ppm.



Commenters during the public comment period asked EPA to apply the biokinetic model to determine a cleanup level. EPA then applied this model as a method to test the three factors initially relied on and the model confirmed EPA's proposed remedy. The model may take on major significance in this litigation.

Discussion: If our remedy is analyzed in the worst possible light, there are flaws in the remedy selection process. EPA's guidance, while properly applied by the region, may have major flaws. ARCO is now suing EPA regarding the validity of the guidance and I am told there is little documentation to support its substance. The literature review alone should not be relied on to determine the site specific remedy to be selected; it may be more general in nature. A review of other RODS was done after the Order was issued. Our remedy is consistent with the other RODS. Consistency between our remedy and other sites is useful, but again, this should only be supporting information--site specific information is best. The State of Illinois recommendation is backed by almost no record.

The PRPs will correctly argue that they have repeatedly requested additional studies in Granite City and the ATSDR study may be just what they were looking for. The PRPs will argue that they have the only risk assessment at the site and it was rejected by EPA without EPA offering a viable alternative (the risk assessment is invalid because EPA no longer believes there is a valid reference dose for lead, a critical input in any risk assessment). NL will argue inadequate information existed at the time of the ROD because EPA failed to keep its commitment to allow a risk assessment or at least a reasonable alternative to a risk assessment. They will then argue that EPA's use of the biokinetic model was improper because we primarily used default values (generic values) rather than site specific values for the various inputs into the model.

Guidance will soon tell us that the model should replace risk assessments for lead. EPA personnel have told me that we used the minimal amount of site specific inputs into our use of the model. While our use was proper, there isn't as great of a comfort zone as there could be. The ATSDR study fill some of those site specific data gaps and may have been useful if it was available before the remedy was determined. A comfort zone in this case may be especially important since the use of the model has not been tested in court as a proper method to replace risk assessments.

The above discussion is intentionally pessimistic--we can make strong arguments for what we did. I am attempting to highlight the risks of allowing this study to take place and examine weaknesses in our position. While I feel our remedy is proper, the study may complicate the litigation and give the PRPs a tool to delay the cleanup.

ATSDR

Quick research on ATSDR indicates that ATSDR was created by Section 104 (i) of CERCLA. While ATSDR is generally supposed to act in cooperation with EPA, it appears to have authority under subsections 104 (i)(7-9) to act independently when it chooses to conduct health studies. ATSDR is funded by EPA. The money it is asking Region V to provide is in addition to ATSDR's usual funding. ATSDR's implementing regulations are found at 42 CFR Part 90. It is possible that ATSDR to not comply with the letter of its regulations in choosing Granite City for its lead study, but I doubt its worth pursuing this point.

Litigation risks of the ATSDR research project

1. Ben Fisherow (DOJ attorney for Sharon Steel Case) and Allan Held (DOJ for NL) have been briefly consulted about the situation. Each has independently told me that the timing of this study is bad and that it runs the risk of complicating the litigation. Risks include reopening the administrative record, releasing draft and preliminary scientific data, slowing down the discovery and trial schedules established by the court, and giving the PRPs more data they can improperly manipulate. Additional risks include placing in jeopardy EPA's ability to recover its costs if we fund the remedy.

2. The PRPs anticipated use of the study is indicated in their correspondence:

The 500 ppm cleanup level for residential areas is not based on science or fact. The fact that a major blood-lead study is being planned for the area by the State of Illinois, after the cleanup value has already been set, is proof that there is serious question about the relationship of the ROD cleanup values and legitimate public health concerns. As the Agency knows, the customer PRPs early on proposed a blood-lead study for the very reason stated above. The customers have always been willing to accept the ROD cleanup levels so long as they are justified by a competent study.

Discussion: The blood screening portion of the study is not proof of anything. It was a portion of the ROD from the beginning and our toxicologists assure me that a blood screening is merely a snapshot in time that can not be used to determine a cleanup level since blood lead levels fluctuate and the people in an area change, but the environmental lead will always be present unless someone removes the contamination. Also, the biokinetic model does not work backwards; knowledge of blood-lead does not help determine environmental cleanup levels, but knowledge of environmental levels does help predict blood-lead levels and therefore helps us determine a proper remedy.

It is the additional portions of ATSDR's study, the portions they are asking us to provide additional funding for, which may pose

the greatest risks of complicating the litigation (although the FRPs are likely to try to misuse the blood screening to complicate the litigation also). The additional environmental data the study will gather can be placed into the biokinetic model and used by the FRPs to improperly manipulate the model's findings as to a proper cleanup level. It is possible information from the study can help or hurt the government's position; it is clear that if a court determines this is necessary information, it will slow down the litigation and, if the site is not a fund lead, it will slow down the cleanup. In the meantime, children will continue to be exposed to what may be permanent mental and physical impairment.

Risks of fighting ATSDR

1. Bad publicity which may spill over into the litigation. ATSDR may make a public issue of this. The State of Illinois almost certainly will if it loses its research money from ATSDR. This will not look good with the public or the Court.
2. We may not wish to alienate ATSDR in a political turf battle for reasons beyond the NL litigation.
3. If ATSDR does what it is threatening, which is to do the study with or without our assistance, a fight may do us more harm than good since we may lose control over their methodologies. This is important for reasons which extend beyond the NL Site, but relate to the usefulness of the data they will accumulate.

The ideal

ATSDR will recognize that they are not helping EPA or the citizens it was created to help, but are hurting them. ATSDR will recognize that it chose the wrong site at the wrong time.

Discussion: It appears that ATSDR has invested too much of its time on this poorly conceived project to recognize or care about the consequences of its proposed course of action. They have chosen to wear blinders and not consider the fact that their desire to obtain scientific data will have negative health implications for the children of Granite City. In my opinion, the NL litigation is better off without this study occurring in Granite City. However, reality may prevent us from accomplishing this goal effectively. ATSDR may have invested too much of its resources into getting this study off the ground to cooperate with us. If we have to fight them, it is possible that even if we win the benefits may not outweigh the costs in the long term. It is clear to me, however, that if the litigation is delayed the real losers will be those exposed to the contamination.

EPA funding of the study should have the minimum conditions:

1. All data should be shared with EPA so that the biokinetic model can be further improved.

2. The scientific protocols used in the study should be EPA approved so that the information from the studies will have increased scientific value by allowing the information to be compatible with and complement other lead studies, such as EPA's tri-city study.

3. ATSDR must agree to provide EPA with a physician or other expert who can testify that the information from the health effects research project ATSDR is proposing is not appropriate for use in determining a remedy at the NL Site and that sufficient information existed at the time of the ROD to make a well reasoned cleanup decision without the information the study will provide. This may provide some damage control to counteract the PRPs presentation on the meaning of the study. However, this will not be complete damage control since the information the study will develop, possibly with Regional money, may very well be relevant for use in the biokinetic model and this may persuade a judge to delay the litigation. Also, presumably, the ATSDR person will not be an expert qualified to discuss how much information is appropriate for determining a remedy. If ATSDR can not provide us with an expert qualified to testify on these matters, we should get a detailed explanation as to why before we agree to give them funding. The explanation will help us evaluate just how badly their research project will jeopardize the litigation.

Discussion: The first and second point above seem self evident. It became clear from discussion at the meeting, however, that neither of these points may occur unless we get ATSDR's up front agreement before we fund their project. Point two, regarding the protocols used, may be relevant to the litigation. Our toxicologist tells me that some of ATSDR's protocols are not scientifically valid and can slant some evidence against EPA at trial. For example, measuring house dust levels through measurements of dusts in vacuum cleaner bags is greatly misleading; the homes with the worst dust concerns are the homes that do not bother to vacuum. The PRPs, using information obtained in the study as it is now designed, would then say the house dust levels are an accurate reflection of the conditions in Granite City, when in fact they may significantly underestimate the exposure levels. The third point is necessary to understand the full implications of the study on the NL litigation.